

REMARKS

At the outset, Applicant's thank Examiners Singh and Saucier for extending the courtesy of a telephone interview to Applicants' representative on March 14, 2007. At the interview, the Albretch reference as well as claims 1, 2, and 8 were discussed.

Status of the Claims

Claims 1-21, including independent claim 1, are pending in this application, with claims 22-43 being in a withdrawn state. Applicants cancel claim 2 without prejudice as the limitations of this claim are now incorporated into amended claim 1. No new subject matter has been added. In light of the amendments and remarks contained herein, reconsideration of claims 1, and 3-21 is respectfully requested.

Claims Rejection under 35 U.S.C. §103(a)

Claims 1, and 3-21 currently stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,534,084 to Vyakarnam et al. (herein "Vyakarnam"), in view of a journal article of Albrecht et al., "Closure of Osteochondral Lesions Using Chondral Fragments and Fibrin Adhesive," *Arch Orthop Trauma Surg*, 101:213-217 (1983) (herein Albrecht), and U.S. Patent No. 5,842,477 to Naughton et al. (herein "Naughton").

Applicants believe that pending claim 1 is patentable over Vyakarnam, Albrecht, and Naughton since none of the cited references disclose a tissue repair implant comprising a tissue carrier matrix comprising a plurality of biocompatible, bioresorbable granules and at least one tissue fragment associated with the tissue carrier matrix. Furthermore, pending claim 1 recites the tissue fragment to have an effective amount of viable cells capable of migrating out of the tissue fragment and populating the matrix. This recitation is also neither taught nor suggested by the cited references. However, to further prosecution of this application, Applicants have amended claim 1 to incorporate the recitation of claim 2, and believe that the amendment places claim 1 and the claims that depend on it in condition for allowance. Such an amendment provides no statement regarding the propriety of the current rejections. Indeed, Applicants maintain the right to prosecute any of the pending claims in a related continuing application.

Amended claim 1 recites a tissue carrier matrix comprising a plurality of biocompatible, bioresorbable granules. The tissue carrier matrix has at least one tissue fragment(s) associated

with the tissue carrier matrix. The tissue fragment(s) has an effective amount of viable cells that can migrate out of the tissue fragment(s) and populate the matrix. Additionally, amended claim 1 recites that the tissue carrier matrix to be *in the form of an injectable suspension*.

The tissue carrier matrix of amended claim 1 can have many advantages. For example, a tissue carrier matrix in the form of an injectable suspension could be delivered to the site repair using a minimally invasive procedure. Another advantage may be derived from using tissue fragments rather than isolated cells. The cells within the tissue fragments are at a lower risk of damage from the shearing forces during the delivery of the implant than isolated cells.

In contrast, none of the cited references disclose the tissue repair implant of amended claim 1. Vyakarnam discloses a biocompatible three dimensional open pore foam that has a gradient composition or microstructure in one or more directions of the foam. Vyakarnam, however, does not teach or suggest a tissue carrier matrix having a plurality of biocompatible bioresorbable granules which are associated with tissue fragments.

Although, the instant office action states that Vyakarnam discloses an injectable tissue carrier matrix (page 3, last paragraph of the instant office action), there is no disclosure in Vyakarnam of the open pore foam being in the form of an injectable suspension as recited by amended claim 1. In fact, the section in Vyakarnam alluded to by the office action, merely teaches methods for molding the foam prior to tissue repair. Amended claim 1 recites that the tissue repair implant be an injectable suspension, (i.e., capable of delivery using an injection syringe (paragraphs 10, 12, 28, 60, and 61 of the specification)). Thus, Vyakarnam does not teach the elements of amended claim 1.

Albretch also fails to teach a tissue carrier matrix that comprises a plurality of granules in association with tissue fragment(s) and is in the form of an injectable suspension. Albretch merely discloses using plugs made of commercially available heterologous collagen foam (Tachotop of Munich) to stop the bleeding from the osteochondral lesions prior to filling the lesions with the modified fibrin glue or a mixture of minced cartilage tissue and fibrin glue. Nowhere, does Albretch disclose the collagen plugs, the fibrin glue, or the mixture of fibrin glue and minced cartilage tissue being in the form of an injectable suspension as required by amended claim 1. Thus, amended claim 1 clearly distinguishes over Albretch.

Finally, Naughton also fails to disclose the claimed tissue repair implant recited by amended claim 1. Naughton merely teaches methods for making and/or repairing diseased cartilage in vivo using a biocompatible, non-living three dimensional scaffold and the use of a periosteal/ perichondrial tissue flap to hold the scaffold in place. However, like Vyakarnam and Albretch, Naughton also fails to mention a tissue a tissue carrier matrix in the form of an injectable suspension as recited by amended claim 1. Furthermore, none of the references in combination teach the elements of amended claim 1. In order to “establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art” (see MPEP §2143.03 citing *In re Royka*, 490 F.2d 981 (CCPA 1974)). Thus, claim 1 is patentable over all three cited references.

Patentability of the Dependent Claims

Claims 3-21 depend on amended claim 1 and incorporate all the limitations of this base claim. Thus, the dependent claims are patentable over the cited references for at least all the same reasons mentioned above for amended claim 1.

Additionally, some of the dependent claims are patentable for other independent reasons. Claim 5, recites the implant of claim 1, wherein the tissue fragment has a particle size in the range of about 0.1 to about 2mm³. Vyakarnam and Naughton do not disclose the use of tissue fragments. Albretch discloses mixing minced cartilage tissue with the fibrin glue, however, Albretch does not disclose the size of the particles of the minced tissue.

Claim 8, recites the implant of claim 1, wherein the average maximum outer diameter of the granules is in the range of about 150 to about 600 µm. None of the cited references disclose a tissue carrier matrix comprising biocompatible bioresorbable granules. Although, Albretch discloses using collagen plugs used to fill osteochondral lesions, Albretch does not disclose a specific range for the size of these plugs. As stated above Vyakarnam and Naughton also do not teach a tissue carrier matrix of biocompatible bioresorbable granules. Vyakarnam discloses a three dimensional porous foam scaffold made of biocompatible bioabsorbable polymer, while Naughton discloses the use of porous felts or mesh as scaffolds. Thus, none of the references disclose the limitations recited in claim 8.

Furthermore, although the Office Action suggests that Albrecht and Naughton both disclose the use of biological components, such components are utilized only with respect to a scaffold and not granules in a tissue carrier matrix. Accordingly, the cited art also fails to teach or suggest many of the recitations of dependent claims 2-21.

Double Patenting

Claims 1-21 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of co-pending U.S. Patent Application No.10/374,772 to Binette et al. (herein the “772 patent”). Applicants will address the nonstatutory obviousness-type double patenting rejection when allowable subject matter has been found.

CONCLUSION

In view of the remarks above, Applicants submit claims 1, and 3-21 are in condition for allowance, and allowance thereof is respectfully requested. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

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Respectfully submitted,



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